

Applicant: Van Tassel et al.  
Serial No.: 09/382,275  
Group Art Unit: 3738

PATENT  
Docket No. 20220-311

B3  
implanting the stent into the tubular organ of the subject prior to or  
following the promoting of the ingrowth of the living cells so as to treat the tubular organ.

### Remarks

This Amendment is filed in response to the Office Action dated April 24, 2002 for the above-referenced application. In this Amendment, claims 1, 43 and 58 are amended. Claims 1, 2, 30, 43-45, 58-64 and 73-75 are currently pending. Reconsideration of the application is requested in view of the amendments and remarks stated herein.

Each of the pending claims stands rejected either under 35 U.S.C. Section 102(b) or 102(e) in view of U.S. Patent No. 5,078,736 to *Behl* and U.S. Patent No. 5,843,172 to *Yan*, respectively. In this regard, an interview was conducted on September 24, 2002 to discuss these rejections. The undersigned and Dr. Robert Schwartz, an inventor in the present application, participated on behalf of the applicant. Examiners Phan and Wilse participated on behalf of the Patent Office.

At the interview, Dr. Schwartz explained that one of the important aspects of the claimed invention is its premise that restenosis is best prevented by *promoting* organized cell growth into the body of a stent. This premise is contrasted with the conventional wisdom of the prior art where cell growth is deemed something that must be *discouraged* around the stent in order to prevent restenosis.

In this regard, Dr. Schwartz further explained that when a stent is formed to have interconnected microholes distributed throughout the stent body along substantially the length of said body as in the presently claimed invention, cells infiltrate those microholes such that the stent itself becomes a living structure that mirrors the tissue makeup of a normal body lumen (e.g., an artery). As such, cell growth in the stent is controlled naturally and does not unnaturally proliferate so as to cause a condition of restenosis.

In view of this discussion, the presently claimed invention was then compared to the *Behl* and *Yan* references asserted in the rejection. As to the *Yan* reference, it was

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explained that the stent disclosed therein does not contain interconnected microholes distributed throughout the stent body along substantially the length of the body as presently claimed. Instead, *Yan* simply discloses a commonly known stent of the prior art where there are large interstitial openings extending directly from an external surface of the stent to the internal surface of the stent. As such, the *Yan* reference does not disclose the structure required to promote an organized growth pattern of infiltrating cells.

Similarly, it was explained that the *Behl* reference also fails to disclose interconnected microholes distributed throughout the stent body along substantially the length of the body as presently claimed. Instead, the *Behl* reference discloses the same conventional prior art design reflected in the *Yan* reference, namely the presence of large interstitial openings extending directly from an external surface of the stent to the internal surface of the stent. As a result, the *Behl* reference also fails to disclose the required structure to promote an organized growth pattern of infiltrating cells.

After considering the points made in the above-referenced discussion, the Examiner agreed that the presently claimed invention was neither anticipated nor rendered obvious by either the *Yan* or *Behl* references. The Examiner, however, also indicated a need to conduct further searching before deeming the claims allowable over the prior art.

In view of the above discussion and in view of the results of the interview, it is submitted that each of the pending claims 1, 2, 30, 43-45, 58-64 and 73-75 are allowable over the prior art and allowance is hereby requested. If however, additional questions or issues arise, the Examiner is cordially encouraged to contact the undersigned telephonically in order to expedite the advancement of this application to issuance.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. No new matter is being added with this amendment. The attached page is captioned "Version With Markings to Show Changes Made."

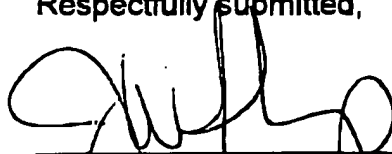
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The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-1901.

Respectfully submitted,

Dated: Sept. 25, 2002

  
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**Version With Markings to Show Changes Made**

Please amend claims 1 and 58 as follows:

1. (Once Amended) An implantable stent comprising a tubular stent body having [surface features adapted] a plurality of interconnected microholes distributed throughout said stent body along substantially the length of said stent body, said plurality of microholes being sufficiently small so as to promote an organized growth pattern of infiltrating cells throughout said stent body.

43. (Once Amended) An active stent comprising a stent according to claim 1 and further comprising live cells growing in said [surface features] interconnected microholes.

58. (Once Amended) A method for treating a tubular body organ in a subject in need thereof, said method comprising:

promoting the ingrowth of living cells in a stent having [surface features sized] a plurality of interconnected microholes distributed within said stent body along substantially the length of said stent body, said plurality of microholes being sufficiently small in size so as to promote ingrowth of the cells, and,

implanting the stent into the tubular organ of the subject prior to or following the promoting of the ingrowth of the living cells so as to treat the tubular [body] organ.